

# PATENT COOPERATION TREATY

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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

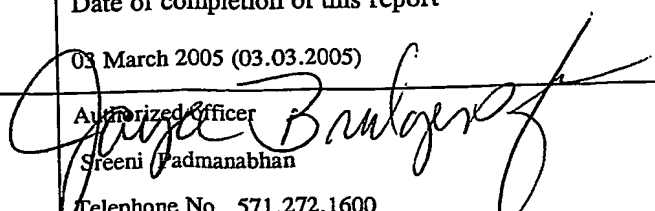
Applicant's or agent's file reference 4115-148-PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/28697	International filing date (day/month/year) 12 September 2003 (12.09.2003)	Priority date (day/month/year) 13 September 2002 (13.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/505, 31/34, 31/36 and US Cl.: 514/256, 275, 461, 466		
Applicant UNIVERSITY OF MARYLAND BIOTECHNOLOGY		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets, including this cover sheet.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 9 sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 24 March 2004 (24.03.2004)	Date of completion of this report 03 March 2005 (03.03.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized Officer  Sreeni Padmanabhan Telephone No. 571.272.1600

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/28697

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed.
- ☒ the description:  
 pages 1-50 as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
 pages NONE, as originally filed  
 pages NONE, as amended (together with any statement) under Article 19  
 pages NONE, filed with the demand  
 pages 51-59, filed with the letter of 19 January 2005 (19.01.2005)
- ☒ the drawings:  
 pages 1-15, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
 pages NONE, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/28697

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims <u>1-54</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-54</u>	NO
Industrial Applicability (IA)	Claims <u>1-54</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Claims 1-54 meet the criteria of PCT Article 33(2) because not a single prior art cited in the International Search Report does expressly disclose the employment of the instant compounds in a pharmaceutical compositions and a method for inducing increased levels of anti-HIV chemokines in activated lymphocytes and a method for modifying synthesis of a receptor ligand to alter extracellular recognition of a receptor by an infectious agent.

Claims 1-54 lack an inventive step under PCT Article 33(3) as being obvious over the combined teachings of the cited prior art, Kempf et al. and Naldini et al.

The combined teachings of the all cited prior art teach that the instant ingredients or compounds or agents are useful in compositions and methods of inhibiting retroviral protease including HIV.

Claims 1-54 meet the criteria of PCT Article 33(4) because the claimed compositions and a method for inducing increased levels of anti-HIV chemokines in activated lymphocytes and a method for modifying synthesis of a receptor ligand to alter extracellular recognition of a receptor by an infectious agent have industrial applicability in the pharmaceutical art.

Applicants' remarks filed 19 January 2005, in response to the Written Opinion mailed January 10, 2005, have been fully considered but not found persuasive in view of the prior art teachings.

----- NEW CITATIONS -----  
NONE